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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,254	07/11/2003	Myrtle Thierry-Palmer	16043-74339	2427

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EXAMINER	
LANKFORD JR, LEON B	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
08/05/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/617,254	THIERRY-PALMER ET AL.	
	Examiner	Art Unit	
	Leon B. Lankford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,8 and 10-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,8 and 10-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Pages 2 & 7 of the specification should be replaced as the current copies are not properly aligned on the page.

Applicant's arguments filed 4/26/2010 have been fully considered but they are not persuasive. The claims (as newly amended/added) remain rejected for the reasons of record. Claim 10 still does not draw a direct correlation between the "calculating" and the "determine salt sensitivity" and claim 12 offers no reference to salt sensitivity at all. Applicant's entire specification points to their invention being for the detection of salt sensitivity and not for a simple binding assay for a known compound and as such applicants are not claiming their invention as required under 35 USC 112 second paragraph. It is suggested that applicant rewrite the claims as such:

14 A method for determining salt sensitivity in an individual comprising

[INSERT STEPS FROM CLAIM 12}

wherein a [INSERT THE RESULT WHICH CORRELATES TO SALT SENSITIVITY] indicates that the individual is salt sensitive.

Further, applicant's vitamin D (or D_3) designations are still not consistent and no discussion as to why that is the case is apparent.

The kit claims remain rejected for the reasons of record. No patentability lies in the combination of a labeled and unlabeled version of the same known compound.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

From the IDS of 6/20/2007, applicant writes:

> The application before the U.S. Patent Office describes and claims a kit for measuring loss of vitamin D binding proteins into urine by assaying for the ability of a sample of urine to bind labeled 25-hydroxyvitamin D_3. The loss of vitamin D binding proteins into urine is an indicator of salt-sensitivity.

The claims do not set forth the invention as recited in the above statement. Applicant's invention would appear to necessarily include the correlation with salt sensitivity and that is now lacking from claim 12. Applicant's claims do not seem to define an invention which results in an evaluation of salt sensitivity of a patient. Applicant needs to make it clear what is being measured from the sample and exactly how it's being measured and then how that correlates to salt sensitivity in order to distinctly claim the subject matter which applicant regards as the invention.

Further, it is unclear what is being claimed as if the invention is designed to be a simple test of the presence of proteins that bind 25-OHD, it is unclear why the samples are split and the excess unlabeled substrate needs to be added.

Applicant's nomenclature is confusing. Applicant sometimes uses the designation "vitamin D" and sometimes "vitamin D_3" seemingly interchangeably and it is unclear what is desired.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca et al(4269777) and Norman et al(3772150) in view of Garman (6054282), Blume(6010861) and Cook(5989854).

DeLuca and Norman both teach radiolabeled 25-OHD to be used in assays. The label is made from non-labeled 25-OHD therefore it would have been obvious at the time the invention was made to make a kit comprising the radiolabeled compound and

unlabeled compound for use in the methods of DeLuca and Norman as a reagent and control.

"When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either ***in the same field or a different one(emphasis added)***. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *KSR v Teleflex* (500 US 398 2007) pages 12-13 of the decision.

It is well known in the art to use both radiolabelled and unlabelled reagents in an assay for reasons including but not limited to controlling the signal produced to be detected. Many examples exist in the art showing assays using both radiolabelled and unlabelled versions of the same reagents in binding assays, e.g. Garman (see e.g. Fig 1), Blume (col 67) and Cook (Col 5-7) and thus it would have been obvious to one of ordinary skill in the art to combine rabiolabelled and unlabelled 25-OHD in a kit.

Applicant is further directed to the same pages 12-13 of *KSR* " … the Court has held that a "patent for a combination which only unites old elements with no change intheir respective functions . . . obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men." Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp., 340 U. S. 147, 152 (1950). This is a principal reason for declining to allow patents for what is obvious. The combination of

familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Lankford whose telephone number is 571-272-0917. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number

for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Leon B Lankford/
Primary Examiner, Art Unit 1651